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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/463,098 | 05/15/2000 | ALFREDO NICOSIA | MEWBURN | 5857 |

7590 05/18/2004

MERCK & CO., INC.
126 E. LINCOLN AVENUE
P.O. BOX 2000 (RY60-30)
RAHWAY, NJ 07065-0907

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| EXAMINER |
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WESSENDORF, TERESA D

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| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 05/18/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,098

Applicant(s)

NICOSIA ET AL.

Examiner

T. D. Wessendorf

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-38,40,43-57 and 97-99 is/are pending in the application.
- 4a) Of the above claim(s) 47-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38,40,43-46 and 97-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Response to Arguments

Applicants' request that claim 46 be examined in the present application. Applicants state that claim 46 is part of group II (claims 32-57), which was previously elected by applicants. Claim 46 is urged as a generic claim encompassing the elected species (Formula II).

In response, in view of applicants' request and argument, i.e., claim 46 is genus of formula II claim 46 will be examined with the elected species, formula II.

Status of Claims

Claims 32-38, 40, 43-57 and 97-99 are pending in the application.

Claims 47-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 32-38, 40, 43-46 and 97-99 are under examination.

Information Disclosure Statement

The listing of references in the specification, pages 88-90, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into

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the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 35-38, 40, 43-44 and 97-98, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In view of the amendments to the claims incorporating the peptide structures, the rejection under the lack of written description in the last Office action no longer applies. However, the amended claims are rejected as follows:

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The as-filed specification does not provide support for amended claim 33 which recites "wherein each of said plurality of peptides". Neither the original claims nor specification recites that the plurality of peptide each contains all the same peptides as recited. This is the more so especially since the specification does not define what constitutes said plurality of peptides. MPEP 714.02 recites that applicants specifically point out where support for the newly added limitations appear in the specification. Also, claim 35 recitation of a composition that further comprises at least one peptide selected from the groups as claimed is not supported in the as-filed specification. Likewise, claim 40 recitation of "...consists of said sequence and hepatitis virus...."

The specification does not describe a composition wherein the entire composition of peptide sequences (108) can be admixed with a pharmaceutically acceptable excipient. Neither does it describe whether single or different types of excipient(s) will be pharmaceutically acceptable with the different (108)-peptide sequences. The specification appears to teach a single peptide that has been formulated with a pharmaceutically acceptable excipient.

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Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-38, 40, 43-46 and 97-99 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of the amendments to the claims, the rejection of the claims in the last Office action no longer applies. However, the newly amended claims are rejected as follows:

A. It is not clear as to the difference between claim 32 drawn to a mixture as compared to claim 33 composition when the same components are recited in both instances. Furthermore, the claimed format of the peptide sequences provide for confusion and ambiguity. It is suggested that applicants recite the peptide sequences in the format as disclosed at e.g., page 14, lines 10-15.

B. Claims 45 and 46 are confusing and appear contradictory with the specification and preceding claims e.g., that Seq. ID. 39 are mixture of peptides. If the intent is to claim the

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individual peptide in the formula II, then it is suggested that the language "selected from the group consisting of" be included. Also, that the full formula of each peptide sequences be recited rather, than in the format, as now claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 46 and 99 are rejected under 35 U.S.C. 102(a) as being anticipated by Puntoriero et al (The EMBO Journal).

The claimed composition of peptide sequences and each of the peptide sequences recited in each of the composition is fully met by the peptide composition of Puntoriero et al. See e.g., page 3522, col. 2, Fig. 1, B; page 3527, Fig. 7, A.

[An In re Katz declaration could overcome this rejection].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

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art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-38, 40, 43-45 and 97-98 rejected under 35 U.S.C.

103(a) as being unpatentable over Puntoriero et al.

Punteriero et al does not disclose the species, as claimed in e.g., claim 32. However, as applicant admitted in the instant REMARKS, page 5, paragraphs 2 and 3, "claim 46 is a generic claim encompassing the elected species (formula II)....and covers the elected species....." It would have been obvious to one having ordinary skill in the art at the time the invention was made to pick and choose the species within a generic claim.

To select features from the prior art to effect results expected from these features is within the purview of 35 USC 103. In re Skoner, 186 USPQ 80 (CCPA 1975).

No claim is allowed.

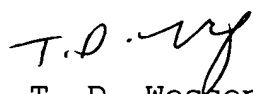
Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the

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organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
May 15, 2004